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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,108	10/08/2004	Ruediger Ridder	05033.0006.PCUS00	8587

27194 7590 05/03/2007

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EXAMINER	
JOYCE, CATHERINE	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,108	RIDDER ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *4,5,18-21,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6-17, and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-26 are pending, and claims 4-5, 18-21, and 25-26 are withdrawn from consideration as being drawn to a non-elected invention

2. Claims 1-3, 6-17 and 22-24 are under examination

3. Applicant's election with traverse of Group I, and the species of E7 as an HPV gene product, an enzyme as a label, a polypeptide as a probe, and HPV 16 as an HPV subtype in the reply filed on March 19, 2007 is acknowledged. Because Applicant did not point out any errors in the restriction requirement, the election is treated as an election without traverse.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 6-17 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the use of the term "predominantly" in claim 2. The term is a relative term which renders the claim indefinite. The term "predominantly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 1-3, 6-17 and 22-24 are indefinite in that claim 1 lacks a method step the clearly relates back to the preamble. Thus, one of skill in the art would not be apprised of the metes and bounds of the invention.

Claims 1-3, 6-17 and 22-24 are indefinite in that the specification lacks a specific definition for the terms "preneoplastic" and "metaplastic" of claim 1, and given the overlapping definitions of these terms as known in the art, one of skill in the art would not know what cell types were being discriminated and thus would not be apprised of the metes and bounds of the invention. In particular, the MSN Encarta definition of metaplasia is defined as "transformation of one type of tissue into another undesirable type, as happens in tumor formation" (http://encarta.msn.com/dictionary_/metaplasmic.html as downloaded on April 29, 2007)

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 6-7, 9, 12-17 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for discriminating $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic or preneoplastic lesions in a biological sample in the course of cytological testing procedures comprising (a) determining the presence or absence of cells overexpression of $p16^{INK4a}$ in said biological sample, (b) determining the presence or absence of cells expressing at least one high risk HPV gene-product in said biological sample, and (c) assessing simultaneous presence of cells expressing high risk HPV gene-products with cells overexpressing $p16^{INK4a}$ or the presence of cells overexpressing $p16^{INK4a}$ alone, wherein the simultaneous presence of cells expressing high risk HPV gene products with cells overexpressing $p16^{INK4a}$ is indicative for neoplastic or preneoplastic lesion, wherein the biological sample comprises cells of the uterine cervix, does not reasonably provide enablement for a claimed method using any biological sample.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to the following:

A method for discriminating $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic or preneoplastic lesions in a biological sample in the course of cytological testing procedures comprising:

(a) determining the presence or absence of cells overexpression of $p16^{INK4a}$ in said biological sample;

(b) determining the presence or absence of cells expressing at least one high risk HPV gene-product in said biological sample; and

(c) assessing simultaneous presence of cells expressing high risk HPV gene-products with cells overexpressing $p16^{INK4a}$ or the presence of cells overexpressing $p16^{INK4a}$ alone;

wherein the simultaneous presence of cells expressing high risk HPV gene products with cells overexpressing $p16^{INK4a}$ is indicative for neoplastic or preneoplastic lesion (**claim 1**),

wherein the high risk HPV gene-products are predominantly expressed in early neoplastic and/or preneoplastic lesions (**claim 2**),

wherein at least one of the HPV gene products is encoded by the HPV E7 gene (**claim 3**),

wherein the HPV gene-product is a polypeptide (**claim 6**),

wherein the neoplastic or preneoplastic lesion are lesions of the anogenital tract (**claim 7**),

wherein the neoplastic or preneoplastic lesion are lesions of the anogenital tract, wherein the lesion of the anogenital tract is a lesion of the uterine cervix (**claim 8**),

wherein the biological sample is a sample containing cells of anogenital origin (**claim 9**),

wherein the biological sample is a sample containing cells of anogenital origin, wherein the cells of anogenital origin are cells originating from the uterine cervix (**claim 10**),

wherein the biological sample is a sample containing cells of anogenital origin, wherein the cells of anogenital origin are cells originating from the uterine cervix, wherein the biological sample is a Pap-smear or a cytological preparation of the cervix uteri (**claim 11**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ (**claim 12**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$, wherein the probe is detectably labeled (**claim 13**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$, wherein the probe is detectably labeled, wherein the label is an enzyme (**claim 14**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$, wherein the probe is a polypeptide (**claim 15**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ wherein the probe is a polypeptide, wherein the probe is an antibody directed against a high risk HPV encoded gene-product or $p16^{INK4a}$ (**claim 16**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ wherein the probe is a polypeptide, wherein the probe is an antibody directed against a high risk HPV encoded gene-product or $p16^{INK4a}$, which comprises an immunocytochemical staining procedure (**claim 17**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ wherein the probe is a polypeptide, wherein detection of the HPV

gene-products and $p16^{INK4a}$ is carried out using nucleic acid probes and polypeptide probes simultaneously (**claim 22**),

wherein the high risk HPV gene-products are gene-products of the cancer associated subtype HPV 16 (**claim 23**),

wherein overexpression of $p16^{INK4a}$ simultaneous to expression of at least one high risk HPV gene products in at least one single cell is determined (**claim 24**).

In the absence of specific definitions of metaplastic and preneoplastic in the specification, it is assumed for examination purposes that metaplastic cells are atypical squamous cells of undetermined significance (ASCUS) that have a low probability of developing into tumors whereas preneoplastic cells are atypical squamous cells of undetermined significance (ASCUS) that have a high probability of developing into to tumors.

The specification teaches the study of the co-detection of HPV gene products and $p16^{INK4a}$ on samples the uterine cervix.

The teaching of the specification cannot be extrapolate to enable the scope of the claims because one of skill in the art could not predict that the claimed method can be used to discriminate $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic or preneoplastic lesions in a biological sample in the course of cytological testing procedure, wherein the biological sample is any sample. In particular, Busken, C et al, (Digestive Disease Week Abstracts and Itinerary Planner, 2003, abstract No:850), teach that there is a difference in COX-2 expression with respect to intensity, homogeneity, localization and prognostic significance between adenocarcinoma of the cardia and distal esophagus, suggesting that these two cancers have different etiology and genetic constitution (last five lines of the abstract). Thus, if two cancers that are seemingly closely related show differences in gene expression, it certainly cannot be predicted,

based on the information in the specification or art or record that any cancers other than cervical cancer will express $p16^{INK4a}$ and HPV gene products. Further, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker to successful clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to the use of biomarkers to detect other cancers. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points (abstract). The essential element of the validation of a marker is the ability to test the marker on clinical material obtained from subjects monitored and to link those marker results with subsequent clinical confirmation of disease. The specification provides insufficient guidance with regard to use of the claimed biological markers in conjunction with samples other than cervical samples. Thus, given the teaching in the art on the heterogeneity of gene expression in cancers and the need to validate cancer markers, and given the lack of guidance on these issue in the specification such as by way of working examples, one of skill in the art could not predict that the invention would function as claimed with regard to any cancer other than cervical cancer. Thus, practice of the invention would require undue experimentation.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 6-17 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaes et al. (2001, Int. J. Cancer 92:276-284) in view of Solomon et al. (2001, J. of the National Cancer Institute 93(4):293-299) and Guccione (Virology 293:20-25 (2002)), as evidenced by von Knebel Doeberitz (2001, Dis. Markers 17(3):123-8 (abstract only).

The claims are drawn to the following:

A method for discriminating $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic or preneoplastic lesions in a biological sample in the course of cytological testing procedures comprising:

(a) determining the presence or absence of cells overexpression of $p16^{INK4a}$ in said biological sample;

(b) determining the presence or absence of cells expressing at least one high risk HPV gene-product in said biological sample; and

(c) assessing simultaneous presence of cells expressing high risk HPV gene-products with cells overexpressing $p16^{INK4a}$ or the presence of cells overexpressing $p16^{INK4a}$ alone;

wherein the simultaneous presence of cells expressing high risk HPV gene products with cells overexpressing $p16^{INK4a}$ is indicative for neoplastic or preneoplastic lesion (**claim 1**),

wherein the high risk HPV gene-products are predominantly expressed in early neoplastic and/or preneoplastic lesions (**claim 2**),

wherein at least one of the HPV gene products is encoded by the HPV E7 gene (**claim 3**),

wherein the HPV gene-product is a polypeptide (**claim 6**),

wherein the neoplastic or preneoplastic lesion are lesions of the anogenital tract (**claim 7**),

wherein the neoplastic or preneoplastic lesion are lesions of the anogenital tract, wherein the lesion of the anogenital tract is a lesion of the uterine cervix (**claim 8**),

wherein the biological sample is a sample containing cells of anogenital origin (**claim 9**),

wherein the biological sample is a sample containing cells of anogenital origin, wherein the cells of anogenital origin are cells originating from the uterine cervix (**claim 10**),

wherein the biological sample is a sample containing cells of anogenital origin, wherein the cells of anogenital origin are cells originating from the uterine cervix, wherein the biological sample is a Pap-smear or a cytological preparation of the cervix uteri (**claim 11**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ (**claim 12**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$, wherein the probe is detectably labeled (**claim 13**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$, wherein the probe is detectably labeled, wherein the label is an enzyme (**claim 14**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$, wherein the probe is a polypeptide (**claim 15**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ wherein the probe is a polypeptide, wherein the probe is an antibody directed against a high risk HPV encoded gene-product or $p16^{INK4a}$ (**claim 16**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ wherein the probe is a polypeptide, wherein the probe is an antibody directed against a high risk HPV encoded gene-product or $p16^{INK4a}$, which comprises an immunocytochemical staining procedure (**claim 17**),

wherein the detection of the HPV gene-products and of $p16^{INK4a}$ is performed using at least one or more probes specific for the HPV gene-products and $p16^{INK4a}$ wherein the probe is a polypeptide, wherein detection of the HPV gene-products and $p16^{INK4a}$ is carried out using nucleic acid probes and polypeptide probes simultaneously (**claim 22**),

wherein the high risk HPV gene-products are gene-products of the cancer associated subtype HPV 16 (**claim 23**),

wherein overexpression of $p16^{INK4a}$ simultaneous to expression of at least one high risk HPV gene products in at least one single cell is determined (**claim 24**).

In the absence of specific definitions of metaplastic and preneoplastic in the specification, it is assumed for examination purposes that metaplastic cells are atypical squamous cells of undetermined significance (ASCUS) that have a low probability of developing into tumors whereas preneoplastic cells are atypical squamous cells of undetermined significance (ASCUS) that have a high probability of developing into to tumors.

Solomon et al. teaches that of the 50 million Pap smears that are performed each year in the United States, more than 5% are reported as abnormal, and that while there is a general consensus by health care providers that cytologically diagnosed high-grade squamous intraepithelial lesions (HSILs) should be evaluated by coloscopy and biopsy, there is no consensus as to the appropriate management of the estimated 3 million women with low-grade squamous intraepithelial lesions (LSILs) or equivocal cytologic abnormalities (atypical squamous cells of undetermined significance [ASCUS]) (page 293). Solomon et al. also teaches that HC 2 testing for cancer-associated HPV DNA is viable option in the management of women with ASCUS in that it has a greater sensitivity to detect cervical intraepithelial neoplasia grade 3 (CIN3) or above and specificity

comparable to a single additional cytologic test (abstract). Solomon et al. also teaches that the HC 2 assay includes a mixture of probes for the following cervical cancer-associated HPV types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68.

Solomon teaches as set forth above but does not teach the detection of $p16^{INK4a}$ in combination with the detection of HPV E7 protein to discriminate metaplasias from neoplastic or preneoplastic lesions.

Klaes et al. teaches that an immunohistochemical analysis of $p16^{INK4a}$ expression levels in a large number of samples of normal cervical tissues, non-neoplastic and pre-neoplastic lesions, and cervical carcinomas indicated that no immunoreactivity was seen in normal epithelia, a sporadic or focal staining pattern was primarily observed in inflammatory legions and reserve cell hyperplasia, a combination of sporadic or focal or diffuse staining patterns were observed in CIN I samples, and a diffuse staining pattern was observed in CIN II, CIN III and invasive carcinomas (Table I, page 279). Thus, Klaes et al. teaches that $p16^{INK4a}$ detection appears to be a sensitive method for the detection of dysplastic cells (abstract), including metaplastic cells and all grades of cervical intraepithelial neoplasia (CIN I-CIN III) (except CIN I associated with low-risk HPV infection) (page 282 and Table 1). Klaes et al. also teaches that although the Pap test has been highly efficient to reduce the morbidity and mortality of cervical cancer; evaluation of the Pap test relies on subjective diagnostic parameters and is affected by a high-rate of false positive and false negative results and that more objective diagnostic parameters are desirable (abstract). Klaes et al. teaches that the anti- $p16^{INK4a}$ antibodies are labeled with peroxidase.

Guccione teaches the antibodies specific for high-risk HPV E7 can be used to detect E7 expression in a cell. As evidenced by von Knebel Doeberitz, expression of the viral E7 protein is required to initiate cervical carcinogenesis and thus E7 is expressed in early neoplastic and/or preneoplastic lesions

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunohistochemical detection of $p16^{INK4a}$, as taught by Klaes, for the cytological component of in the cytological/HPV detection combination method taught by Solomon to discriminate $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic or preneoplastic lesions in a biological sample in the course of cytological testing. One of skill in the art would have been motivated to make the substitution because of the advantages taught by Klaes in the use of objective diagnostic parameters in the avoiding the false negatives and false positives of the subjective Pap test. One of skill in the art would have had a reasonable expectation of success in making the substitution because of the success taught in Klaes of detecting metaplastic, preneoplastic and neoplastic cells by detecting the expression of $p16^{INK4a}$. Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the immunohistochemical method of Guccione for the detection of high risk HPV E7 protein for the nucleic assay method of Solomon. One of skill in the art would have been motivated to make the substitution because of the greater ease of implementation of immunohistochemical methods versus nucleic assay methods. One of skill in the art would have had a reasonable expectation of success in making the substitution because of the success taught by Guccione in detecting high-risk HPV E7 levels in cells.

10. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Ungar

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Catherine Joyce
Examiner
Art Unit 1642